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Group: 1617
Confirmation No.: 1013
Application No.: 09/870,899
Invention: **Animal Food and Method**
Applicant: Wilson, et al.
Filed: May 31, 2001
Attorney
Docket: 834460-68474
Examiner: S. Jiang

Certificate Under 37 CFR 1.8(a)

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on October 21, 2002

Garla L. Twyman
(Signature)

Garla L. Twyman
(Printed Name)

DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. DONALD E. ORR

Assistant Commissioner for Patents
Washington, D.C. 20231

I declare as follows:

1. I have been employed by United Feeds, Inc., the assignee of the captioned application, since 1984. Currently, I am President and Chief Operating Officer of United Feeds, Inc., and I have held this position since 1997. As President and Chief Operating Officer of United Feeds, Inc., I am responsible for increasing global market share through new product development of animal feed supplements, including Fertilium™, the animal feed supplement that is the subject of the method claimed in the captioned application. A copy of my current Curriculum Vitae is attached as Exhibit F.

2. I have reviewed the captioned patent application, including claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70. The invention of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70

is directed to a method of increasing the reproductive performance of female swine by administering to the female swine a feed composition comprising marine animal products. The reproductive performance of female swine is increased by increasing the number of live births or total births to a female swine, by increasing the farrowing rate, or by increasing the uniformity of birth weight of offspring.

3. Fertilium™, an animal feed additive that contains marine animal products, is the United Feeds, Inc. product that is the subject of the method claimed in the captioned application. Fertilium™ was introduced into the marketplace in February of 2002, and has met with great commercial success in the 8 months it has been on the market. The commercial success of Fertilium™ has been more rapid than expected based on my experience in new product development in the animal feed supplement market.

4. Fertilium™ has met with commercial success in the short time that it has been on the market because Fertilium™ consistently produces good results in increasing reproductive performance in sows. Swine producers have been impressed by the consistent increases in reproductive performance in sows obtained by feeding Fertilium™ to the sows leading to the commercial success of this product. The commercial success of Fertilium™ is evidenced by the following monthly sales figures for the 2002 fiscal year:

<u>Time Period</u>	<u>Pounds Sold</u>	<u>Value of Sales</u> <u>(U.S. Dollars)</u>
Feb. '02	88,020	83,677.09
March '02	105,600	100,389.70
April '02	118,455	112,610.43
May '02	109,088	103,705.60
June '02	113,850	108,232.64
July '02	135,158	128,489.30
Aug. '02	129,075	122,706.44
Sept. '02*	140,000	133,092.40
Oct. '02*	150,000	142,599.00
Nov. '02*	162,000	154,006.92
Dec. '02*	175,000	166,365.50
		Total = 1,355,875.02

* Projected based on current market analysis and projected sales.

5. The commercial success of Fertilium™ is further evidenced by the following annualized estimates of usage and total sows affected:

<u>Time Period</u>	<u>Pounds Sold/ Month</u>	<u>Total Pounds/Year</u>	<u>Sows Affected</u>
Feb.-Aug. '02	129,075	1,548,900	147,514.29
2002*	175,000	2,100,000	200,000.00
2003*	525,000	6,300,000	600,000.00
2004*	875,000	10,500,000	1,000,000.00

* Projected based on current market analysis and projected sales.

6. Thus, the value of sales (in U.S. dollars) in the first seven months that Fertilium™ has been on the market is approximately \$760,000, and, based on current market analysis projections, sales are predicted to reach \$1,355,875 by the end of 2002, about three times this amount during 2003, and about five times this amount during 2004. Approximately 150,000 sows are already being fed Fertilium™, and current market analysis projections predict that Fertilium™ will be fed to approximately 200,000 sows by the end of 2002, 600,000 sows by 2003, and 1,000,000 sows by 2004. Approximately 130,000 pounds of Fertilium™ are currently being sold per month by United Feeds, Inc., and, based on current market analysis projections, it is predicted that approximately 175,000 pounds will be sold per month by the end of 2002, 525,000 pounds per month by 2003, and 875,000 pounds per month by 2004.

7. The commercial acceptance of Fertilium™ is directly related to the claimed invention (*i.e.*, a method of increasing the reproductive performance of female swine by administering a feed composition containing marine animal products to the female swine). Fertilium™ is the only swine feed supplement on the market that contains marine animal products comprising C₂₀ and C₂₂ omega-3 fatty acids and esters thereof. The swine production business is very competitive and margins are very close. Swine producers have been impressed by the consistently good results obtained (*i.e.*, increased reproductive performance in sows) when sows

are fed Fertilium™ and, thus, the effectiveness of Fertilium™ in consistently increasing reproductive performance of sows has led to the commercial success of the claimed invention.

8. Furthermore, Fertilium™ already has a market share that is three to five times greater than a flaxseed-containing product, and Fertilium™ has only been on the market for about 8 months. The flaxseed-containing product is an animal feed supplement containing ground flaxseed that is sold for use in increasing the reproductive performance of female swine, and the flaxseed-containing product had been on the market for a number of years before Fertilium™ was introduced to the marketplace. Therefore, Fertilium™, the product that embodies the claimed method, has met with great commercial success, and Fertilium™ has supplanted a flaxseed-containing product in the animal feed supplement market in the short time that Fertilium™ has been on the market.

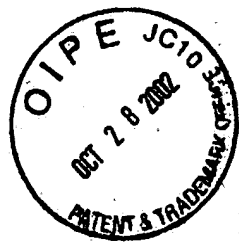
All statements made herein are of my own knowledge are true and all statements made on information and belief are believed to be true; these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 10/8/02

By: Dr. Donald E. Orr

Dr. Donald E. Orr
President and Chief Operating Officer
of United Feeds, Inc.

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Garla L. Twyman
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Garla L. Twyman

(Printed Name)

DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. DOUGLAS M. WEBEL

Assistant Commissioner for Patents
Washington, D.C. 20231

I declare as follows:

1. I am the Swine Nutritionist at United Feeds, Inc. I received a Doctorate of Animal Sciences degree from the University of Illinois, Department of Animal Sciences in 1998. My research interests have included the Animal Sciences, in particular animal nutrition and reproduction. I have authored or co-authored numerous publications in the areas of my research interest. A copy of my current Curriculum Vitae is attached as Exhibit C.

2. I understand that in the Office Action dated April 23, 2002 in the captioned U.S. patent application, the Examiner rejected claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,110,592 (hereinafter the '592 patent) in view of Boudreaux et al. and statements on pages 1-3 of the specification of the

captioned application. I have read and understand the specification of the captioned application, the claims as they have been amended, and the Office Action dated April 23, 2002. I have also considered other sources of information including the '592 patent, Abayasekara et al. (attached as Exhibit A), and Quackenbush et al. (attached as Exhibit B). I have considered the Examiner's conclusion that the claimed invention is obvious over the '592 patent in view of Boudreaux et al. and statements on pages 1-3 of the specification of the captioned application.

3. I disagree with the Examiner's conclusion that the claims of the captioned application are obvious over the '592 patent in view of Boudreaux et al. and statements on pages 1-3 of the specification of the captioned application. The Examiner asserts that the '592 patent teaches that omega-3 fatty acids such as alpha-linolenic acid, eicosapentenoic acid, and docosahexanoic acid in flaxseed, fed to animals as a component of animal feed, increase the number of live births to a female swine. The Examiner also states that 1.) the '592 patent teaches that flaxseed is known to contain omega-3 fatty acids such as alpha-linoleic acid, eicosapentenoic acid, and docosahexanoic acid, 2.) the '592 patent does not disclose that the omega-3 fatty acids are derived from fish oil, 3.) the '592 patent does not disclose the use of omega-3 fatty acids in combination with omega-6 fatty acids in a composition and a method for increasing the reproductive performance such as by increasing the number of live births to a female swine, and 4.) the '592 patent does not disclose the ratio of omega-6 fatty acids to omega-3 fatty acids in the composition. The Examiner indicates that Boudreaux et al. discloses a ratio of omega-6 to omega-3 fatty acids that is within the claims of the application.

4. The Examiner further indicates that the Applicants state on pages 1-3 of the specification that 1.) omega-3 fatty acids such as eicosapentenoic acid and docosahexanoic acid and docosapentaenoic acid are well known to be derived from fish oils and marine algae (page 2, lines 13-14), 2.) omega-6 fatty acids are known to increase the number of live births in animals (page 2, lines 24-25), 3.) salmon oil is known to be used in animal food (page 2, lines 26-27), 4.) omega-3 fatty acids in particular are known to be useful to increase female animal fertility (page

2, lines 29-30), and 5.) salmon oil is known to contain both omega-3 and omega-6 fatty acids (page 3, lines 1-3).

5. The Examiner contends that, based upon all of the above-described disclosures and statements, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ omega-3 and omega-6 fatty acids derived from fish oil in Applicants' claimed method for increasing the reproductive performance of female swine and to optimize the ratio of these fatty acids in the composition. I understand the Examiner's conclusion, but I do not agree that the invention of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 is obvious over the '592 patent in view of Boudreaux et al. and statements on pages 1-3 of Applicants' specification.

6. The claims of the captioned application are directed to a method of increasing the reproductive performance of a female swine by administering to the female swine a feed composition comprising marine animal products.

7. The Examiner contends that the '592 patent teaches that omega-3 fatty acids in an edible composition comprising flaxseed are useful in a method for increasing the number of live births in female swine. However, contrary to the Examiner's conclusion, the '592 patent does not teach that omega-3 fatty acids increase the number of live births in female swine when fed to the animal in a feed composition. The '592 patent teaches that flaxseed increases the number of live births in female swine when included in a feed composition. In this regard, the '592 patent describes administering to female swine a feed composition comprising ground flaxseed to increase the number of live births in female swine.

8. Moreover, the Applicant of the '592 patent merely speculates that the omega-3 fatty acid, linolenic acid, might be the component in flaxseed that increases the fertility of female animals, but acknowledges that other unknown compounds may be responsible for this effect. For example, in column 3, lines 10-24, of the '592 patent specification, the Applicant states that "[w]hile not wanting to be bound by the following explanation, it also appears that the linolenic

acid in the flaxseed improves the fertility of the animal . . . flaxseed, however, may contain *other compounds which affect immunity and fertility but may be unknown at this time.*"

(emphasis added). Accordingly, the Applicant of the '592 patent merely speculates that omega-3 fatty acids in flaxseed might increase the fertility of female swine, and clearly acknowledges that there are other unknown components in flaxseed that may be responsible for this effect.

Therefore, the '592 patent teaches that flaxseed causes an increase in live births in female swine, and the Applicant of the '592 patent merely speculates that omega-3 fatty acids might be a component in flaxseed that increases the fertility of female animals. Thus, the method of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 is not obvious over the '592 patent simply because marine animal products, as specified in Applicants' claims, contain omega-3 fatty acids. The teaching of the '592 patent that flaxseed causes an increase in live births in female swine does not render obvious a method of increasing the reproductive performance of female swine by administering a composition comprising marine animal products to female swine.

9. The Examiner asserts that the Applicants state on page 2, lines 29-30, of the specification that "omega-3 fatty acids in particular are known to be useful to increase female animal fertility" (statement 4 above) and that claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 are obvious over the '592 patent in view of this statement and Boudreaux et al. Contrary to the Examiner's contention, the Applicants state on page 2, lines 29-30, that "the effects of linseed oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied (Abayasekara, *et al.*, 1999)." Moreover, when taken in the context of the Abayasekara et al. reference (cited by the Applicants in reference to this statement) Applicants' statement does not mean that "omega-3 fatty acids in particular are known to be useful to increase female animal fertility," but means that the effects of omega-3 fatty acids on fertility in cattle, sheep, and rats have been studied.

10. In Abayasekara et al. (attached as Exhibit A), the effects of polyunsaturated fatty acids (PUFAs; *e.g.*, omega-3 and omega-6 fatty acids) on fertility were studied. The authors first

studied the effects of PUFAs on the types of prostaglandins and eicosanoids synthesized in response to feeding animals PUFAs because there are changes in prostaglandin and eicosanoid synthesis in response to administration of PUFAs to animals and these changes may be relevant to fertility. The authors emphasize that the changes in prostaglandin and eicosanoid synthesis are unpredictable in response to the administration of PUFAs to animals. For example, the authors tested the effects of α -linolenic acid on prostaglandin synthesis in animals. The authors make the following statement about these studies on page 279, column 1:

In contrast, this dietary regime was also associated with changes in tissue phospholipid levels of PUFAs: increases in linoleic (18:2n-6), gamma linolenic (18:3n-6) and dihomogamma linolenic (20:3n-6) acids and a decrease in AA. The changes are not as expected and reinforce the need for experimental verification through monitoring of PUFAs and prostaglandin generation in the tissue(s) of interest in animals exposed to different PUFA diets.

The authors further studied the effects of dietary manipulations of PUFAs on eicosanoid production and state that “[i]t is, therefore, clear that dietary manipulations of PUFAs can have major effects on eicosanoid production, although these are hard to predict.” See page 279, column 2. Therefore, Abayasekara et al. teaches that the effects of dietary PUFAs on prostaglandin and eicosanoid synthesis are unpredictable.

11. Furthermore, the authors of Abayasekara et al. indicate that the effects of dietary PUFAs on fertility are unpredictable. For example, the authors state on page 280, column 1, paragraph 2, that “[a]nimals on a high n-3 diet had increased ovulations in comparison with rats on a control diet whereas a diet high in n-6 PUFAs caused a decrease in the number of ova released.” On page 281, column 2, paragraph 1, the authors contrast the effects on fertility of feeding cattle a diet supplemented with tallow versus yellow grease. The authors state that:

Abomasal infusion of cattle with tallow (high in PUFAs but with only 2% linoleic acid) increased plasma PGFM ($\text{PGF}_{2\alpha}$) concentrations in response to an oxytocin injection in comparison to treatment with yellow grease containing 20% linoleic acid. Yellow grease in fact impaired the ability of the uterus to secrete $\text{PGF}_{2\alpha}$ possibly through inhibition of cyclooxygenase.

The authors also state with respect to male animals (page 282, column 2, paragraph 2) that “n-3 PUFA (linolenic acid) supplementation in the diet caused a marked decrease in testicular size and

loss of fertility, whereas n-6 PUFA (linoleic acid) supplementation had no effect on testis size or fertility.” Moreover, the authors conclude (page 282, column 2, last paragraph) that “[o]ur relative lack of knowledge means that it is impossible to predict at present whether particular dietary manipulations, which may be desirable from a human health viewpoint, will enhance or reduce fertility. Therefore, it is essential that further research into this general area is carried out before any changes in feed in terms of PUFA composition, are implemented.” Accordingly, Abayasekara et al. teaches that the effects of dietary supplementation with PUFAs on prostaglandin and eicosanoid synthesis and on fertility are difficult to predict.

12. Therefore, Applicants’ statement taken in the context of Abayasekara et al. cannot mean that omega-3 fatty acids are known to be useful to increase female animal fertility because Abayasekara et al. teaches that the effects of omega-3 and omega-6 fatty acids on female fertility are unpredictable. In this regard, the Applicants’ statement that “the effects of linseed oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied” taken in the context of Abayasekara et al. does not mean, as the Examiner suggests, that “omega-3 fatty acids in particular are known to be useful to increase female animal fertility,” but rather Applicants’ statement means that the effects of omega-3 fatty acids on increased female fertility have been studied.

13. Accordingly, the teaching of the ‘592 patent that flaxseed causes an increase in live births in female swine in combination with Applicants’ statement that “the effects of linseed oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied” does nothing to render obvious a method of increasing the reproductive performance of female swine by administering to the animals a feed composition comprising marine animal products even if marine animal products contain omega-3 fatty acids. Furthermore, in light of the teaching of Abayasekara et al. that the effects of omega-3 fatty acids on reproductive performance are unpredictable, it would not have been

obvious to a skilled artisan that marine animal products would increase female reproductive performance even though marine animal products contain omega-3 fatty acids.

14. The Examiner also asserts that the Applicants state on page 2, lines 24-25 of the specification that “omega-6 fatty acids are known to increase the number of live births in animals” (statement 2 above). Contrary to the Examiner’s assertion, the Applicants state on page 2, lines 24-25, of the amended specification that “linseed oil and corn oil have been used in animal feed as a source of omega-6 fatty acids to increase the number of live births and to increase the number of weaned rats (Quackenbush, *et al.*, 1942).” Again, when this statement is taken in the context of Quackenbush *et al.* (cited by the Applicants in reference to this statement), the statement does not mean that “omega-6 fatty acids are known to increase the number of live births in animals” as the Examiner suggests.

15. In Quackenbush *et al.* (attached as Exhibit B) two different diets were fed to rats and the effect of these diets on reproductive performance was determined. The diets were a “rice-extract diet” and a “yeast diet.” These diets contained a coconut oil supplement (see page 1), a substantial lipid content derived from the rice extract and the yeast composition (see Table 2), and each of the diets was also supplemented with ethyl linolate or ethyl linolenate. Thus, the rats were not fed a diet containing only omega-6 fatty acids, but were fed omega-6 fatty acids in combination with many other lipids. Accordingly, Quackenbush *et al.* does not show that omega-6 fatty acids increase the number of live births in rats (*i.e.*, a mixture of lipids was fed to the rats). Therefore, the statement that “linseed oil and corn oil have been used in animal feed as a source of omega-6 fatty acids to increase the number of live births and to increase the number of weaned rats” does not mean that omega-6 fatty acids alone are “known to increase the number of live births in animals” as the Examiner suggests.

16. Accordingly, the teaching of the ‘592 patent that flaxseed causes an increase in live births in female swine in combination with Applicants’ statement taken in the context of Quackenbush *et al.* does not render obvious the method of claims 1-20, 23, 25, 41, 60-62, 65, 67,

69, and 70. Applicants' statement does not suggest that omega-6 fatty acids alone increase female fertility so the combination of the '592 patent and Applicants' statement does nothing to suggest that marine animal products would increase female reproductive performance even if marine animal products contain omega-6 fatty acids. Furthermore, in light of the teaching of Abayasekara et al. that the effects of omega-6 fatty acids on reproductive performance are unpredictable, it would not have been obvious to a skilled artisan that marine animal products would increase female reproductive performance even though marine animal products contain omega-6 fatty acids. Moreover, rats were used in the studies described in Quakenbush et al., and, accordingly, these studies do not render obvious Applicants' method of increasing the reproductive performance of female swine by administering marine animal products to the female swine. Thus, a method of increasing the reproductive performance of female swine by administering to the animals a feed composition comprising marine animal products is not obvious over the '592 patent in combination with Applicants' statement.

17. The Examiner also indicates that Applicants' statements that fish oils and marine algae contain omega-3 fatty acids (statement 1 above), that salmon oil contains both omega-3 and omega-6 fatty acids (statement 5 above), and that salmon oil is known to be used in animal food (statement 3 above) in combination with the '592 patent render obvious the method of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70. In light of the teachings of Abayasekara et al. that the effects of omega-3 and omega-6 fatty acids on reproductive performance are unpredictable, Applicants' statements that fish oils and marine algae contain omega-3 fatty acids and that salmon oil contains omega-3 and omega-6 fatty acids do nothing to indicate that marine animal products would increase the reproductive performance of female swine. Applicants' statement that salmon oil is known to be used in animal food does nothing more to indicate that marine animal products would increase the reproductive performance of female swine. Thus, the teaching of the '592 patent that flaxseed increases reproductive performance of female swine in

combination with Applicants' statements 1, 3, and 5 does not render obvious the method of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70.

18. The Examiner further indicates that Boudreaux et al. discloses a ratio of omega-6 to omega-3 fatty acids that is within the instant claims. Boudreaux et al. does nothing to overcome the above-described insufficiencies of the '592 patent and of Applicants' statements cited by the Examiner.

19. With respect to original claim 7 and amended claims 60-62, 65, 67, and 69, these claims require that a feed composition comprising marine animal products containing "C₂₀ and C₂₂ omega-3 fatty acids or esters thereof" be administered to the female swine. Flaxseed lacks C₂₀ and C₂₂ omega-3 fatty acids or esters thereof (see attached Exhibit E). Accordingly, because flaxseed lacks C₂₀ and C₂₂ omega-3 fatty acids or esters thereof and claims 7, 60-62, 65, 67, and 69 require that the feed composition contains C₂₀ and C₂₂ omega-3 fatty acids or esters thereof, the subject matter of claims 7, 60-62, 65, 67, and 69 cannot be obvious over the '592 patent alone or in combination with any of Applicants' statements and Boudreaux et al.

20. In sum, based on my background, training, and experience in this field I submit the following:

A.) With respect to the Examiner's rejection of claims 1-18, 41, and 69 for indefiniteness, the definition of "reproductive performance" was well-known in the art at the time of filing the captioned application.

B.) The '592 patent teaches that flaxseed, not omega-3 fatty acids, causes an increase in live births in female swine.

C.) The statement 4 that "the effects of linseed oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied" taken in the context of Abayasekara et al. does not mean, as the Examiner suggests, that "omega-3 fatty acids in particular are known to be useful to

increase female animal fertility,” but rather this statement means that the effects of omega-3 fatty acids on increased female fertility have been studied.

D.) The statement 2 taken in the context of Quakenbush et al. does not suggest that omega-6 fatty acids alone increase female fertility.

E.) Statement 2 is directed to Quakenbush et al. which describes studies in which the reproductive performance of rats was increased.

F.) Accordingly, the teaching of the ‘592 patent that flaxseed causes an increase in live births in female swine in combination with statement 2 or 4 does nothing to render obvious a method of increasing the reproductive performance of female swine by administering to the animals a feed composition comprising marine animal products even if marine animal products contain omega-3 and omega-6 fatty acids.

G.) Furthermore, in light of the teaching of Abayasekara et al. that the effects of omega-3 and omega-6 fatty acids on reproductive performance are unpredictable, it would not have been obvious to a skilled artisan that marine animal products would increase female reproductive performance even though marine animal products contain omega-3 and omega-6 fatty acids.

H.) In view of the teaching of Abayasekara et al. that the effects of omega-3 and omega-6 fatty acids on reproductive performance are unpredictable, the statements that fish oils and marine algae contain omega-3 fatty acids (statement 1), that salmon oil contains both omega-3 and omega-6 fatty acids (statement 5), and that salmon oil is known to be used in animal food (statement 3) do nothing in combination with the ‘592 patent to render obvious Applicants’ claimed method.

I.) Boudreaux et al. does nothing to overcome the above-described insufficiencies of the ‘592 patent and of the statements cited by the Examiner.

J.) With respect to claims 7, 60-62, 65, 67, and 69, these claims cannot be obvious over the ‘592 patent alone or in combination with Applicants’ statements and

Boudreaux et al. because flaxseed lacks C₂₀ and C₂₂ omega-3 fatty acids or esters thereof and claims 7, 60-62, 65, 67, and 69 require that the feed composition contains C₂₀ and C₂₂ omega-3 fatty acids or esters thereof.

All statements made herein are of my own knowledge are true and all statements made on information and belief are believed to be true; these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated:

10-17-02

By:

Douglas M. Webel

Dr. Douglas M. Webel

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(Signature)

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(Printed Name)

DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. STEPHEN K. WEBEL

Assistant Commissioner for Patents
Washington, D.C. 20231

I declare as follows:

1. I am currently the Director of Reproduction Research and Development at United Feeds, Inc., and have worked in the animal sciences area as the Senior Physiologist at Abbott Laboratories, as a Professor of Animal Sciences at Illinois State University, and as the Swine Business Manager at Purina Mills, Inc. I received a Doctorate of Animal Sciences degree from the University of Illinois, Department of Animal Sciences in 1972. My research interests have included the Animal Sciences, in particular the physiology of animal reproduction. I have been elected to numerous offices in professional organizations. A copy of my current Curriculum Vitae is attached as Exhibit D.

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2. I understand that in the Office Action dated April 23, 2002 in the captioned U.S. patent application, the Examiner rejected claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,110,592 (hereinafter the '592 patent) in view of Boudreaux et al. and statements on pages 1-3 of the specification of the captioned application. I have read and understand the specification of the captioned application, the claims as they have been amended, and the Office Action dated April 23, 2002. I have also considered other sources of information including the '592 patent, Abayasekara et al. (attached as Exhibit A), and Quackenbush et al. (attached as Exhibit B). I have considered the Examiner's conclusion that the claimed invention is obvious over the '592 patent in view of Boudreaux et al. and statements on pages 1-3 of the specification of the captioned application.

3. I disagree with the Examiner's conclusion that the claims of the captioned application are obvious over the '592 patent in view of Boudreaux et al. and statements on pages 1-3 of the specification of the captioned application. The Examiner asserts that the '592 patent teaches that omega-3 fatty acids such as alpha-linolenic acid, eicosapentenoic acid, and docosahexanoic acid in flaxseed, fed to animals as a component of animal feed, increase the number of live births to a female swine. The Examiner also states that 1.) the '592 patent teaches that flaxseed is known to contain omega-3 fatty acids such as alpha-linoleic acid, eicosapentenoic acid, and docosahexanoic acid, 2.) the '592 patent does not disclose that the omega-3 fatty acids are derived from fish oil, 3.) the '592 patent does not disclose the use of omega-3 fatty acids in combination with omega-6 fatty acids in a composition and a method for increasing the reproductive performance such as by increasing the number of live births to a female swine, and 4.) the '592 patent does not disclose the ratio of omega-6 fatty acids to omega-3 fatty acids in the composition. The Examiner indicates that Boudreaux et al. discloses a ratio of omega-6 to omega-3 fatty acids that is within the claims of the application.

4. The Examiner further indicates that the Applicants state on pages 1-3 of the specification that 1.) omega-3 fatty acids such as eicosapentenoic acid and docosahexanoic acid

and docosapentaenoic acid are well known to be derived from fish oils and marine algae (page 2, lines 13-14), 2.) omega-6 fatty acids are known to increase the number of live births in animals (page 2, lines 24-25), 3.) salmon oil is known to be used in animal food (page 2, lines 26-27), 4.) omega-3 fatty acids in particular are known to be useful to increase female animal fertility (page 2, lines 29-30), and 5.) salmon oil is known to contain both omega-3 and omega-6 fatty acids (page 3, lines 1-3).

5. The Examiner contends that, based upon all of the above-described disclosures and statements, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ omega-3 and omega-6 fatty acids derived from fish oil in Applicants' claimed method for increasing the reproductive performance of female swine and to optimize the ratio of these fatty acids in the composition. I understand the Examiner's conclusion, but I do not agree that the invention of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 is obvious over the '592 patent in view of Boudreaux et al. and statements on pages 1-3 of Applicants' specification.

6. The claims of the captioned application are directed to a method of increasing the reproductive performance of a female swine by administering to the female swine a feed composition comprising marine animal products.

7. The Examiner contends that the '592 patent teaches that omega-3 fatty acids in an edible composition comprising flaxseed are useful in a method for increasing the number of live births in female swine. However, contrary to the Examiner's conclusion, the '592 patent does not teach that omega-3 fatty acids increase the number of live births in female swine when fed to the animal in a feed composition. The '592 patent teaches that flaxseed increases the number of live births in female swine when included in a feed composition. In this regard, the '592 patent describes administering to female swine a feed composition comprising ground flaxseed to increase the number of live births in female swine.

8. Moreover, the Applicant of the '592 patent merely speculates that the omega-3 fatty acid, linolenic acid, might be the component in flaxseed that increases the fertility of female animals, but acknowledges that other unknown compounds may be responsible for this effect. For example, in column 3, lines 10-24, of the '592 patent specification, the Applicant states that "[w]hile not wanting to be bound by the following explanation, it also appears that the linolenic acid in the flaxseed improves the fertility of the animal . . . flaxseed, however, may contain other compounds which affect immunity and fertility but may be unknown at this time." (emphasis added). Accordingly, the Applicant of the '592 patent merely speculates that omega-3 fatty acids in flaxseed might increase the fertility of female swine, and clearly acknowledges that there are other unknown components in flaxseed that may be responsible for this effect. Therefore, the '592 patent does not teach that omega-3 fatty acids in flaxseed cause an increase in live births in female swine, but rather teaches that ground flaxseed has this effect. The Applicant of the '592 patent merely speculates that omega-3 fatty acids might be a component in flaxseed that increases the fertility of female animals. Thus, the method of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 is not obvious over the '592 patent simply because marine animal products, as specified in Applicants' claims, contain omega-3 fatty acids. The teaching of the '592 patent that flaxseed causes an increase in live births in female swine does not render obvious a method of increasing the reproductive performance of female swine by administering a composition comprising marine animal products to female swine.

9. The Examiner asserts that the Applicants state on page 2, lines 29-30, of the specification that "omega-3 fatty acids in particular are known to be useful to increase female animal fertility" (statement 4 above) and that claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70 are obvious over the '592 patent in view of this statement and Boudreaux et al. Contrary to the Examiner's contention, the Applicants state on page 2, lines 29-30, that "the effects of linseed oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied (Abayasekara, *et al.*, 1999)." Moreover,

when taken in the context of the Abayasekara et al. reference (cited by the Applicants in reference to this statement) Applicants' statement does not mean that "omega-3 fatty acids in particular are known to be useful to increase female animal fertility," but means that the effects of omega-3 fatty acids on fertility in cattle, sheep, and rats have been studied.

10. In Abayasekara et al. (attached as Exhibit A), the effects of polyunsaturated fatty acids (PUFAs; e.g., omega-3 and omega-6 fatty acids) on fertility were studied. The authors first studied the effects of PUFAs on the types of prostaglandins and eicosanoids synthesized in response to feeding animals PUFAs because there are changes in prostaglandin and eicosanoid synthesis in response to administration of PUFAs to animals and these changes may be relevant to fertility. The authors emphasize that the changes in prostaglandin and eicosanoid synthesis are unpredictable in response to the administration of PUFAs to animals. For example, the authors tested the effects of α -linolenic acid on prostaglandin synthesis in animals. The authors make the following statement about these studies on page 279, column 1:

In contrast, this dietary regime was also associated with changes in tissue phospholipid levels of PUFAs: increases in linoleic (18:2n-6), gamma linolenic (18:3n-6) and dihomogamma linolenic (20:3n-6) acids and a decrease in AA. The changes are not as expected and reinforce the need for experimental verification through monitoring of PUFAs and prostaglandin generation in the tissue(s) of interest in animals exposed to different PUFA diets.

The authors further studied the effects of dietary manipulations of PUFAs on eicosanoid production and state that "[i]t is, therefore, clear that dietary manipulations of PUFAs can have major effects on eicosanoid production, although these are hard to predict." See page 279, column 2. Therefore, Abayasekara et al. teaches that the effects of dietary PUFAs on prostaglandin and eicosanoid synthesis are unpredictable.

11. Furthermore, the authors of Abayasekara et al. indicate that the effects of dietary PUFAs on fertility are unpredictable. For example, the authors state on page 280, column 1, paragraph 2, that "[a]nimals on a high n-3 diet had increased ovulations in comparison with rats on a control diet whereas a diet high in n-6 PUFAs caused a decrease in the number of ova

released.” On page 281, column 2, paragraph 1, the authors contrast the effects on fertility of feeding cattle a diet supplemented with tallow versus yellow grease. The authors state that:

Abomasal infusion of cattle with tallow (high in PUFAs but with only 2% linoleic acid) increased plasma PGFM (PGF_{2α}) concentrations in response to an oxytocin injection in comparison to treatment with yellow grease containing 20% linoleic acid. Yellow grease in fact impaired the ability of the uterus to secrete PGF_{2α} possibly through inhibition of cyclooxygenase.

The authors also state with respect to male animals (page 282, column 2, paragraph 2) that “n-3 PUFA (linolenic acid) supplementation in the diet caused a marked decrease in testicular size and loss of fertility, whereas n-6 PUFA (linoleic acid) supplementation had no effect on testis size or fertility.” Moreover, the authors conclude (page 282, column 2, last paragraph) that “[o]ur relative lack of knowledge means that it is impossible to predict at present whether particular dietary manipulations, which may be desirable from a human health viewpoint, will enhance or reduce fertility. Therefore, it is essential that further research into this general area is carried out before any changes in feed in terms of PUFA composition, are implemented.” Accordingly, Abayasekara et al. teaches that the effects of dietary supplementation with PUFAs on prostaglandin and eicosanoid synthesis and on fertility are difficult to predict.

12. Therefore, Applicants’ statement taken in the context of Abayasekara et al. cannot mean that omega-3 fatty acids are known to be useful to increase female animal fertility because Abayasekara et al. teaches that the effects of omega-3 and omega-6 fatty acids on female fertility are unpredictable. In this regard, the Applicants’ statement that “the effects of linseed oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied” taken in the context of Abayasekara et al. does not mean, as the Examiner suggests, that “omega-3 fatty acids in particular are known to be useful to increase female animal fertility,” but rather Applicants’ statement means that the effects of omega-3 fatty acids on increased female fertility have been studied.

13. Accordingly, the teaching of the ‘592 patent that flaxseed causes an increase in live births in female swine in combination with Applicants’ statement that “the effects of linseed

oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied” does nothing to render obvious a method of increasing the reproductive performance of female swine by administering to the animals a feed composition comprising marine animal products even if marine animal products contain omega-3 fatty acids. Furthermore, in light of the teaching of Abayasekara et al. that the effects of omega-3 fatty acids on reproductive performance are unpredictable, it would not have been obvious to a skilled artisan that marine animal products would increase female reproductive performance even though marine animal products contain omega-3 fatty acids.

14. The Examiner also asserts that the Applicants state on page 2, lines 24-25 of the specification that “omega-6 fatty acids are known to increase the number of live births in animals” (statement 2 above). Contrary to the Examiner’s assertion, the Applicants state on page 2, lines 24-25, of the amended specification that “linseed oil and corn oil have been used in animal feed as a source of omega-6 fatty acids to increase the number of live births and to increase the number of weaned rats (Quackenbush, *et al.*, 1942).” Again, when this statement is taken in the context of Quackenbush et al. (cited by the Applicants in reference to this statement), the statement does not mean that “omega-6 fatty acids are known to increase the number of live births in animals” as the Examiner suggests.

15. In Quackenbush et al. (attached as Exhibit B) two different diets were fed to rats and the effect of these diets on reproductive performance was determined. The diets were a “rice-extract diet” and a “yeast diet.” These diets contained a coconut oil supplement (see page 1), a substantial lipid content derived from the rice extract and the yeast composition (see Table 2), and each of the diets was also supplemented with ethyl linolate or ethyl linolenate. Thus, the rats were not fed a diet containing only omega-6 fatty acids, but were fed omega-6 fatty acids in combination with many other lipids. Accordingly, Quackenbush et al. does not show that omega-6 fatty acids increase the number of live births in rats (*i.e.*, a mixture of lipids was fed to the rats). Therefore, the statement that “linseed oil and corn oil have been used in animal feed as a source

of omega-6 fatty acids to increase the number of live births and to increase the number of weaned rats” does not mean that omega-6 fatty acids alone are “known to increase the number of live births in animals” as the Examiner suggests.

16. Accordingly, the teaching of the ‘592 patent that flaxseed causes an increase in live births in female swine in combination with Applicants’ statement taken in the context of Quakenbush et al. does not render obvious the method of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70. Applicants’ statement does not suggest that omega-6 fatty acids alone increase female fertility so the combination of the ‘592 patent and Applicants’ statement does nothing to suggest that marine animal products would increase female reproductive performance even if marine animal products contain omega-6 fatty acids. Furthermore, in light of the teaching of Abayasekara et al. that the effects of omega-6 fatty acids on reproductive performance are unpredictable, it would not have been obvious to a skilled artisan that marine animal products would increase female reproductive performance even though marine animal products contain omega-6 fatty acids. Moreover, rats were used in the studies described in Quakenbush et al., and, accordingly, these studies do not render obvious Applicants’ method of increasing the reproductive performance of female swine by administering marine animal products to the female swine. Thus, a method of increasing the reproductive performance of female swine by administering to the animals a feed composition comprising marine animal products is not obvious over the ‘592 patent in combination with Applicants’ statement.

17. The Examiner also indicates that Applicants’ statements that fish oils and marine algae contain omega-3 fatty acids (statement 1 above), that salmon oil contains both omega-3 and omega-6 fatty acids (statement 5 above), and that salmon oil is known to be used in animal food (statement 3 above) in combination with the ‘592 patent render obvious the method of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70. In light of the teachings of Abayasekara et al. that the effects of omega-3 and omega-6 fatty acids on reproductive performance are unpredictable, Applicants’ statements that fish oils and marine algae contain omega-3 fatty acids and that

salmon oil contains omega-3 and omega-6 fatty acids do nothing to indicate that marine animal products would increase the reproductive performance of female swine. Applicants' statement that salmon oil is known to be used in animal food does nothing more to indicate that marine animal products would increase the reproductive performance of female swine. Thus, the teaching of the '592 patent that flaxseed increases reproductive performance of female swine in combination with Applicants' statements 1, 3, and 5 does not render obvious the method of claims 1-20, 23, 25, 41, 60-62, 65, 67, 69, and 70.

18. The Examiner further indicates that Boudreaux et al. discloses a ratio of omega-6 to omega-3 fatty acids that is within the instant claims. Boudreaux et al. does nothing to overcome the above-described insufficiencies of the '592 patent and of Applicants' statements cited by the Examiner.

19. With respect to original claim 7 and amended claims 60-62, 65, 67, and 69, these claims require that a feed composition comprising marine animal products containing "C₂₀ and C₂₂ omega-3 fatty acids or esters thereof" be administered to the female swine. Flaxseed lacks C₂₀ and C₂₂ omega-3 fatty acids or esters thereof (see attached Exhibit E). Accordingly, because flaxseed lacks C₂₀ and C₂₂ omega-3 fatty acids or esters thereof and claims 7, 60-62, 65, 67, and 69 require that the feed composition contains C₂₀ and C₂₂ omega-3 fatty acids or esters thereof, the subject matter of claims 7, 60-62, 65, 67, and 69 cannot be obvious over the '592 patent alone or in combination with any of Applicants' statements and Boudreaux et al.

20. In sum, based on my background, training, and experience in this field I submit the following:

A.) With respect to the Examiner's rejection of claims 1-18, 41, and 69 for indefiniteness, the definition of "reproductive performance" was well-known in the art at the time of filing the captioned application.

B.) The '592 patent teaches that flaxseed, not omega-3 fatty acids, causes an increase in live births in female swine.

C.) The statement 4 that “the effects of linseed oil, and omega-3 fatty acids in particular, on increased sperm fertility and female fertility, applicable to cattle, sheep, and rats, have been studied” taken in the context of Abayasekara et al. does not mean, as the Examiner suggests, that “omega-3 fatty acids in particular are known to be useful to increase female animal fertility,” but rather this statement means that the effects of omega-3 fatty acids on increased female fertility have been studied.

D.) The statement 2 taken in the context of Quakenbush et al. does not suggest that omega-6 fatty acids alone increase female fertility.

E.) Statement 2 is directed to Quakenbush et al. which describes studies in which the reproductive performance of rats was increased.

F.) Accordingly, the teaching of the ‘592 patent that flaxseed causes an increase in live births in female swine in combination with statement 2 or 4 does nothing to render obvious a method of increasing the reproductive performance of female swine by administering to the animals a feed composition comprising marine animal products even if marine animal products contain omega-3 and omega-6 fatty acids.

G.) Furthermore, in light of the teaching of Abayasekara et al. that the effects of omega-3 and omega-6 fatty acids on reproductive performance are unpredictable, it would not have been obvious to a skilled artisan that marine animal products would increase female reproductive performance even though marine animal products contain omega-3 and omega-6 fatty acids.

H.) In view of the teaching of Abayasekara et al. that the effects of omega-3 and omega-6 fatty acids on reproductive performance are unpredictable, the statements that fish oils and marine algae contain omega-3 fatty acids (statement 1), that salmon oil contains both omega-3 and omega-6 fatty acids (statement 5), and that salmon oil is known to be used in animal food (statement 3) do nothing in combination with the ‘592 patent to render obvious Applicants’ claimed method.

I.) Boudreaux et al. does nothing to overcome the above-described insufficiencies of the '592 patent and of the statements cited by the Examiner.

J.) With respect to claims 7, 60-62, 65, 67, and 69, these claims cannot be obvious over the '592 patent alone or in combination with Applicants' statements and Boudreaux et al. because flaxseed lacks C₂₀ and C₂₂ omega-3 fatty acids or esters thereof and claims 7, 60-62, 65, 67, and 69 require that the feed composition contains C₂₀ and C₂₂ omega-3 fatty acids or esters thereof.

All statements made herein are of my own knowledge are true and all statements made on information and belief are believed to be true; these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dated: *October 17, 2002*

By: *Stephen K. Weibel*

Dr. Stephen K. Weibel